

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO

FILED  
U.S. DISTRICT COURT  
COLORADO  
2000 AUG -1 PM 3:08  
JAMES R. HANSPEAKER  
CLERK

PEOPLE FOR THE ETHICAL )  
TREATMENT OF ANIMALS, et al., )

Plaintiffs, )

v. )

CAROL M. BROWNER, Administrator )  
of the United States Environmental )  
Protection Agency, )

Defendant. )

BY \_\_\_\_\_ DEP. CLK

Civil Action No. 00-D-1090

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ANSWER

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Defendant Carol M. Browner, Administrator of the United States Environmental Protection Agency, answers the numbered paragraphs of the Complaint as follows:

1. This paragraph consists of the Plaintiffs' characterization of the action to which no answer is required.
2. The first sentence of this paragraph consists of legal conclusions to which no answer is required. Defendant admits the remainder of the allegations in this paragraph.
3. This paragraph consists of legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that this Court has subject matter jurisdiction over the claims in the Complaint.
4. With respect to the first and second sentences of this paragraph, Defendant lacks sufficient knowledge or information to either admit or deny. Defendant admits that all three Plaintiff organizations

received  
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are signatories to the citizens' petition for rulemaking described in this paragraph. The remainder of the allegations of this paragraph consist of legal conclusions to which no answer is required.

5. Defendant admits the first sentence of this paragraph. The second sentence of this paragraph consists of legal conclusions to which no answer is required. The third sentence of this paragraph consists of the Plaintiffs' characterization of the action to which no answer is required.

6. This paragraph consists of legal conclusions to which no answer is required.

7. Defendant admits the allegations in the first sentence of this paragraph. The Council on Environmental Quality proposal cited in this paragraph speaks for itself and is the best evidence of its contents, and Defendant denies the allegation in the second sentence of this paragraph.

8. Defendant admits that this paragraph accurately quotes from Section 2 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601, except that "chemical substances and mixtures that present an unreasonable risk of injury" as reported in this paragraph is actually "chemical substances and mixtures which present an unreasonable risk of injury" in § 2601(b)(2).

9. This paragraph consists of the legal conclusions of the Plaintiffs to which no answer is required.

10. This paragraph consists of the legal conclusions of the Plaintiffs to which no answer is required.

11. This paragraph consists of the legal conclusions of the Plaintiffs to which no answer is required.

12. Defendant admits that this paragraph accurately quotes from Section 8(a) of TSCA, 15 U.S.C. § 2607(a), and asserts that the remaining allegations are legal conclusions to which no answer is

required.

13. The first sentence of this paragraph consists of legal conclusions to which no answer is required. Defendant denies the second sentence of this paragraph and states that high production volume (HPV) chemicals constitute a subset of the list of chemical substances called for in 15 U.S.C. § 2607(b)(1).

14. Defendant admits that this paragraph accurately quotes from Section 8(c) of TSCA, 15 U.S.C. § 2607(c).

15. Defendant admits that this paragraph accurately quotes from Section 8(d) of TSCA, 15 U.S.C. § 2607(d).

16. Defendant admits that this paragraph accurately quotes from Section 8(e) of TSCA, 15 U.S.C. § 2607(e), except that “maintains information which reasonably support” as reported in this paragraph is actually “ obtains information which reasonably supports” in § 2607(e), and asserts that the remaining allegations are legal conclusions to which no answer is required.

17. Defendant admits that, in 1997, the Environmental Defense Fund (“EDF”) issued a report asserting that basic toxicity data was lacking for 75% of chemicals selected from a set of 468 chemicals that EDF termed “high priority chemicals.” Defendant admits that EPA issued its own report detailing the extent to which it appeared that basic toxicity data were lacking for HPV chemicals. Defendant admits that Vice President Gore called on government, industry and the environmental community to develop a plan to fill the data gaps. Defendant admits that in October 1998 EPA announced the launch of the HPV Challenge Program (the “Program”), a program to make screening-level hazard data publicly available, whether by the submission of existing data or by the development of data if none

exist. Defendant denies the remainder of the allegations in this paragraph.

18. Defendant admits that (1) the HPV Challenge Program called for development of data by 2004, or submission of existing data, pertaining to approximately 2,800 HPV chemicals because much basic hazard data are currently not available, (2) the Program contemplated either testing sponsored by chemical companies or the submission of existing data, (3) EPA committed that if scientifically adequate hazard screening data were submitted pertaining to chemicals under the HPV Challenge Program EPA would not issue rules requiring testing to obtain the same data on those chemicals, and (4) over 440 chemical companies (either independently or through industry consortia) have agreed to sponsor chemicals under the HPV Challenge Program. Defendant lacks sufficient knowledge to either admit or deny the allegations concerning whether the testing industry geared up for an influx of work. Defendant denies the remainder of the allegations in this paragraph.

19. Defendant admits that, subsequent to meeting with animal welfare organizations, EPA further underscored to participants in the HPV Challenge Program that use of existing data has been a central aspect of the Program and agreed to defer certain animal testing until November 2001 in the event that some additional non-animal test methods may become validated and available in the meantime. Defendant denies the remainder of the allegations in this paragraph.

20. Defendant denies the allegations in this paragraph.

21. Defendant denies the allegations in this paragraph.

22. Defendant admits that the HPV Challenge Program is voluntary and admits that any companies not participating in the Program would not submit data under the Program. Defendant lacks sufficient knowledge or information to either admit or deny that approximately 400 chemical companies

are not participating in the Program. Defendant denies the remaining allegations in this paragraph.

23. Defendant admits that toxicity data generally constitute only a component of the complete assessment of risk. Defendant denies the remainder of the allegations in this paragraph.

24. Defendant denies the first two sentences of Paragraph 24. With respect to the subparagraphs thereof:

a. Defendant admits the likelihood that some undisclosed data exist concerning some of the 2800 chemicals covered by the Program, including data concerning both hazard and exposure. Defendant lacks sufficient knowledge or information to either admit or deny the location, form, or accessibility of such data. Defendant denies the remainder of the allegations in this paragraph.

b. Defendant lacks sufficient knowledge or information to either admit or deny allegations concerning (1) what any undisclosed data may indicate concerning the chemical substances to which the data pertain, and (2) what the history of products liability litigation in the United States demonstrates concerning the disclosure practices of manufacturers, processors and distributors of products or components of products. Defendant denies the remainder of the allegations in this subparagraph.

c. With respect to the first and second sentences of this subparagraph, Defendant lacks sufficient knowledge or information to either admit or deny. Defendant admits that data showing that particular chemicals are not toxic, or that health and the environment are not exposed to risk of injury from them, contribute to the objective of determining which chemicals, if any, should undergo further assessment and which of those, if any, should be regulated. Defendant denies the remainder of the allegations in this paragraph.

25. With respect to the first two sentences of this paragraph, (1) Plaintiffs' petition speaks for itself and is the best evidence of its contents, and (2) any allegations as to the effects of the rules sought in the petition constitute legal conclusions to which no answer is required. Defendant lacks sufficient knowledge or information to either admit or deny allegations concerning what any data submitted under the rules requested by the Plaintiffs would indicate concerning the toxicity of, or exposure to, chemical substances subject to the rules.

26. Defendant admits that Plaintiffs petitioned the Administrator under 15 U.S.C. § 2620(a) to initiate certain proceedings. Defendant asserts that Plaintiffs' petition speaks for itself and is the best evidence of its contents, and any allegations as to the effects of the rules sought in the petition constitute legal conclusions to which no answer is required. Defendant notes that the Preliminary Assessment Information Manufacturer's Report cited in the paragraph is numbered 7710-35.

27. Defendant denies the allegations in this paragraph.

28. Defendant denies the allegations in this paragraph.

29. Defendant denies the allegations in this paragraph.

#### **GENERAL DENIAL**

Defendant denies each and every allegation of the complaint not specifically admitted. To the extent that any allegation of fact in the complaint remains unanswered, Defendant denies such allegation.

Defendant denies each and every Prayer for Relief.

#### **FIRST DEFENSE**

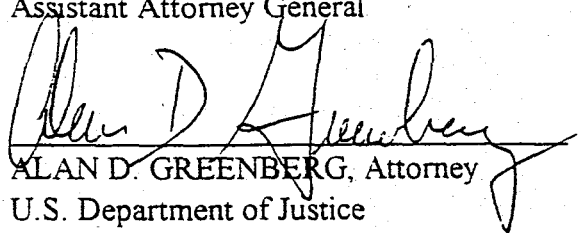
The complaint fails to state a claim upon which relief can be granted.

WHEREFORE, Defendant Carol M. Browner denies that Plaintiffs are entitled to any relief from the Court and requests that the Court dismiss the complaint against the Defendant with prejudice.

Respectfully submitted this 1st day of August 2000.

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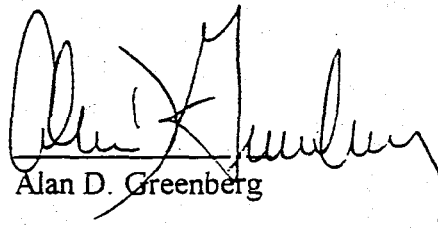
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## CERTIFICATE OF SERVICE

I hereby certify that on this 1<sup>st</sup> day of August 2000, a true and correct copy of the foregoing Answer was deposited in the United States mail, first class, postage pre-paid, addressed to the following counsel:

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